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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,096	11/24/1999	BERNARD ACKERMAN	409897	5859

30954 7590 05/19/2004

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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/449,096

Applicant(s)

ACKERMAN, BERNARD

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9 and 11-23 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,7,9,11-13,15,16,22 and 23 is/are rejected.
- 7) ☒ Claim(s) 5 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The Request for Continued Examination has been granted and entered into the file. The Amendment to the claims dated 3/12/04 has been entered into the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 9, 11 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Todd et al (US pat# 5,423,745). Todd teaches a balloon catheter that includes a flexible tubular body with a single lumen having an external opening. See figures 1 and 2. The lumen has a second opening communicating with the interior of the balloon. See figure 2. A syringe is used to dispense fluid through the lumen. The external opening generates a back flow, which causes the fluid in the lumen to inflate the balloon. See 9:9-17.

Claims 1-2, 4 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Briscoe et al (US pat# 6,458,096). Briscoe discloses a balloon catheter that includes a flexible tubular body with a single lumen having an external opening (84 or 106). See figures 7,8,10,11. The lumen has a second opening communicating with the interior of the balloon (90 or 116). The

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external opening generates a back flow, which causes the fluid in the lumen to inflate the balloon. See 7:52-23 or 9:34-57.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd. Todd meets the claim limitations as described above but fails to include the balloon being made from polyurethane. However, at the time of the invention, it would have been obvious to make the balloon of Todd from any biocompatible material including polyurethane. Applicant has not disclosed that polyurethane provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the material taught by Todd or polyurethane because both materials are commonly used in catheter balloon construction and both are used for their compatibility with the human body.

Claims 6-7, 9, 11, 13, 15-16 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briscoe. Briscoe meets the claim limitations as described above but fails to include using a syringe to inflate the balloon or the balloon being made from polyurethane.

At the time of the invention, it would have been obvious to use a syringe to inflate the balloon of Briscoe. It is well known in the art to use a syringe to inflate a catheter balloon. See Todd above. Additionally, Applicant has not disclosed that using the syringe to inflate the balloon provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either fluid from a pressurized source other than a syringe or a syringe because both inflation devices are commonly used in catheter balloon inflation.

At the time of the invention, it would have been obvious to make the balloon of Todd from any biocompatible material including polyurethane. Applicant has not disclosed that polyurethane provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the material taught by Todd or polyurethane because both materials are commonly used in catheter balloon construction and both are used for their compatibility with the human body.

Claims 3 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Todd or Briscoe in further view of Grayzel (US Pat# 4,921,479). Both Todd and Briscoe independently meet the claim limitations as described above but neither describe a moveable catheter introducer sheath. However, Grayzel discloses a catheter sheath for guidance of a catheter into a blood vessel. See Summary of invention. The sheath provides a semi-stiff plastic tubular structure to help guide the catheter into the blood vessel.

At the time of the invention, it would have been obvious to use the catheter sheath with both the inventions of Todd and Briscoe, independently. In general, catheter are either introduced into the vascular with use of a guidewire or catheter introducer to guide the catheter to the target location within the body. Both Todd and Briscoe are single lumen catheters where the single lumen is used for fluid introduction into the body. Using a guidewire would not be advantageous inside the lumen with the fluid for introduction into the body. The motivation for using an external sheath, such as the one disclosed by Grayzel, would have been to provide the catheter with guiding capabilities without having to use a guidewire.

Allowable Subject Matter

Claims 5 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams *CSW.*
May 13, 2004


LOAN H. THANH
PRIMARY EXAMINER